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14. ABSTRACT

Purpose: This study measured outcomes of a nurse-managed diabetes foot clinic on foot wound rates, health care costs, and changes in health status in adults with diabetes. **Design:** This study reflects results of a two-group randomized, controlled trial. **Sample:** Participants were 126 adults with diabetes for more than 5 years and high- or very-high-risk feet. **Instrumentation:** Participants were randomized to control (n = 62) or treatment (n = 64) using stratified assignment by risk. All received diabetic-foot self-care education and foot assessment. Controls were seen very three months. Treatment participants with high-risk feet were seen every 3 months and those with very-high-risk feet, every 2 months. **Methods:** Five nurses with 90% inter-rater reliability used a standard assessment form to rate relevant foot conditions and 10-g monofilament testing for neuropathy on 10 sites on the plantar aspect of the foot. Treatment included nail clipping, callus filing, corn removal, padding, footwear selection, and special shoes as needed. Analysis: The data were analyzed using analysis of variance, chi-square, t tests, linear regression, and frequency calculations. A health care economist used a bootstrapping technique to determine costs of care during the 1-year study. Cost data were compared to Medicare reimbursement costs for related common procedure terminology (CPT) codes. **Findings**: A total of 74 wounds occurred in the control group and 62 in the treatment group. Change in wound prevalence was significant (p = .03). There was no effect on overall health status. Costs were higher in the treatment group by an average of $312 per participant. No study participants were hospitalized for foot wounds. Hospital data showed that, during the study period, 46 admissions for diabetic foot wounds occurred in nonstudy patients who received little foot care. **Nursing Implications:** This study suggests that a nurse-managed diabetes-foot clinic might reduce overall diabetes costs despite the slightly higher expense per patient.

15. SUBJECT TERMS

Prevention of amputation in patients with diabetes, Nurse-Managed Clinic, Diabetic Foot Preventive Care, Reduction of foot wounds

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III. ABSTRACT

Purpose

This study measured outcomes of a nurse-managed diabetes foot clinic on foot wound rates, health care costs, and changes in health status in adults with diabetes.

Design

This study reflects results of a two-group randomized, controlled trial.

Sample

Participants were 126 adults with diabetes for more than 5 years and high- or very-high-risk feet.

Instrumentation

Participants were randomized to control (n = 62) or treatment (n = 64) using stratified assignment by risk. All received diabetic-foot self-care education and foot assessment. Controls were seen every three months. Treatment participants with high-risk feet were seen every 3 months and those with very-high-risk feet, every 2 months.

Methods

Five nurses with 90% inter-rater reliability used a standard assessment form to rate relevant foot conditions and 10-g monofilament testing for neuropathy on 10 sites on the plantar aspect of the foot. Treatment included nail clipping, callus filing, corn removal, padding, footwear selection, and special shoes as needed.

Analysis

The data were analyzed using analysis of variance, chi-square, *t* tests, linear regression, and frequency calculations. A health care economist used a bootstrapping technique to determine costs of care during the 1-year study. Cost data were compared to Medicare reimbursement costs for related common procedure terminology (CPT) codes.

Findings

A total of 74 wounds occurred in the control group and 62 in the treatment group. Change in wound prevalence was significant ($p = .03$). There was no effect on overall health status. Costs were higher in the treatment group by an average of $312 per participant. No study participants were hospitalized for foot wounds. Hospital data showed that, during the study period, 46 admissions for diabetic foot wounds occurred in nonstudy patients who received little foot care.

Nursing Implications

This study suggests that a nurse-managed diabetes-foot clinic might reduce overall diabetes costs despite the slightly higher expense per patient.

IV. INTRODUCTION

Diabetes occurs in epidemic proportions in the United States today, affecting approximately 20.8 million people (National Diabetes Information Clearing House, 2007). One person in 16 is diagnosed with the disease. Chronic multi-system effects of diabetes are dramatic. Among other complications, 5.3 to 8.1 people per 1,000 with diabetes will have a lower extremity wound and subsequent amputation each year. Fifteen percent of patients with diabetes will experience a foot wound at some time during their lives. An analysis of data collected through the Behavioral Risk Factor Surveillance System for 2000–2002 showed a 12% occurrence of foot wounds among U.S. adults with diabetes during this time (Centers for Disease Control and Prevention [CDC], 2003). The report also notes that foot ulcers and lower-extremity amputations (LEAs) could be reduced by 44% to 85% with good foot care.

Health care and human costs related to lower extremity wounds and subsequent amputations are staggering. Healing of diabetic foot wounds costs individuals or insurance programs between $7,000 and $45,000 each (Wu & Armstrong, 2006). A toe amputation,, on average, costs $22,700 and for an above-the-knee amputation $51,300 (in 2001 dollars) (Driver, Madsen, & Goodman, 2005).

Costs of amputation include wound care, hospitalization for amputation, medications, special footwear, and a rehabilitation hospital for physical/occupational therapy until patients are functional again. Some bilateral amputees may require $10,000 motorized wheelchairs for mobility (Gilcreast personal experience, 2007). Most patients with diabetes affected by amputation are between 45 and 64 years of age and working. The amputation results in reduced work productivity and income, as well as significant alteration in health status. Numerous studies (CDC, 2003; Bild, Selby, Pomeroy, Browner, Braveman, & Showstack, 1989; Driver et al.,

2005) have shown that amputations and their related costs can be reduced by half through basic foot-care education for patients, easy access to foot evaluation and care, and primary care interventions, especially when wounds first begin. "…[M]any foot catastrophes in people with diabetes begin with an apparently trivial lesion, which breaks the skin and leaves a portal for infection" (Foster & Edmonds, 2001, p. 46). "Healthcare systems are often symptom-led and this approach has proved disastrous for people with diabetes" (Foster & Edmonds, p. 48).

Currently, clinical practice guidelines for patients with diabetes (American Diabetes Association, 2007) do not provide a comprehensive approach to the prevention of foot wounds. Providers are required only to visually inspect the feet for wounds and perform 10-g monofilament testing for diabetic peripheral neuropathy once a year. Kirkman, Williams, Caffrey, and Marrero (2002) showed that primary care physicians' adherence to diabetes guidelines overall was suboptimal, with a mere 15% examining feet in diabetes patients as recommended. After interventions were initiated with feedback, compliance increased to only 42%. In addition, in most medical treatment facilities, follow-up appointments and access to care is the patient's responsibility and the process is often not user-friendly.

This study is the first to evaluate a comprehensive nursing approach to the prevention of foot ulceration in diabetes patients by measuring the outcomes of a diabetes foot clinic staffed by advanced-practice nurses. The foot clinic personnel identified and treated patients with diabetes who were at high- to very-high risk for foot wounds. The study demonstrates the effectiveness of using nursing interventions to prevent life- and limb-threatening complications of diabetes.

Literature Review

A literature search of the Cochrane Library Database of Abstracts and Reviews of Effects using the keywords *diabetic foot*, *nursing*, and *prevention* revealed three relevant systematic

reviews (Maciejewski, Reiber, Smith, Wallace, Hayes, & Boyko, 2004; Mason, O'Keeffe, Hutchinson, McIntosh, & Booth, 2007; Mason, O'Keeffe, McIntosh, Hutchinson, Booth, & Young, 2007). The reviews included research from 1980 onward, published in MEDLINE, EMBASE, CINAHL, HealthStar, PsychLIT, Science Citation Index, and Social Science Citation Index. In each area, the best research evidence was reviewed. A review of thousands of patients showed that education alone is not a placebo treatment (as intended by the investigators in this study); rather, education can reduce foot wounds by 10% more than a control treatment (Mason, O'Keeffe, Hutchinson et al.). However, the reviewers did not identify the best method of educating or assessing long-term effects of foot education. In the present study, education was provided to the control group, thus making it a "light" intervention rather than a placebo and reducing the effect size between group means for the outcomes.

The reviewers found "No formal comparative evidence…to indicate that any optimal arrangement of health care professionals exists for diabetic foot care" (Mason, O'Keeffe, McIntosh et al., 2007, p. 3). The study of interventions for patients at high risk for foot wounds was inconclusive. Authors of these systematic reviews concluded that available research is insufficient to answer the important questions related to diabetic-foot preventive care and footwear. However, in clinics where people with diabetes receive well-organized, regular care with rapid referral of problems to specialists, wound morbidity can be significantly reduced (Mason, O'Keeffe, McIntosh et al.). Treatment cost-effectiveness was also lacking in existing studies, and a study of cost-effectiveness of interventions was recommended.

The current study fulfills this recommendation and is unique in linking the goals of reducing foot wounds in diabetes patients, conserving financial resources for the organization, and providing a unique view into the patients' perceptions of their health status as evidenced by

the limitations of diabetes. This study is noteworthy in that it measured patients' perceptions of health status in relationship to functional status. Quality of life was previously studied in terms of patients having to deal with testing their blood glucose levels and managing their diabetes medications, but has not been assessed in terms of overall functional status as a dynamic effect on the human system (Maciejewski et al., 2004).

V. SCOPE OF THE STUDY

This study measured outcomes of a nurse-managed diabetes-foot clinic for adults with diabetes mellitus at a Southwest Texas Army medical center by providing and coordinating comprehensive foot care. Clinic nursing staff identified patients with diabetes at risk for ulceration and provided standardized care and follow-up, including (1) education for patients in basic foot care and selection of footwear, (2) primary foot care on a regular basis, and (3) coordination of access to care based on wound-risk classification or occurrence of a foot wound. The study compared costs of foot care, health care, and health status outcomes between the control and experimental groups. Both groups of participants received assessment, basic foot care education, and scheduled examinations. Control participants were seen every 3 months. Experimental group participants were seen every 3 months if they had a high-risk for ulceration or every 2 months if they had very-high risk for ulceration based upon the Veterans Affairs Puget Sound Health Care System foot classification system (Ahroni, 2003).

Specific Aims

Benefits of preventive diabetic foot care include a reduced number of wounds, improved quality of life for patients, and reduced costs to health care systems (Armstrong, 2001). Currently, clinical practice guidelines (American Diabetes Association, 2007) for patients with diabetes do not provide a comprehensive approach to the prevention of foot wounds. Providers are required only to visually inspect the feet for wounds and perform 10-g monofilament testing once a year. A study by Kirkman, Williams, Caffrey, and Marrero (2002) showed that primary

care physicians' adherence to diabetes guidelines overall was suboptimal; only 15% of physicians regularly perform foot exams.

This study is the first to provide a more comprehensive approach to the prevention of foot wounds in patients with diabetes. The nurse-managed diabetes foot clinic had a threefold focus: (1) The patient's risk to develop a foot wound was identified, with treatment and follow-up based upon risk classification and the patient's response to care. Primary care providers were notified of treatments and progress as well as referrals for care involving the patient's diabetes. (2) An efficient system of notifying patients of their appointments in advance was used so that they did not have to seek foot care. (3) The patients' perceptions of their health status in relationship to functional status were measured to determine the impact of care on health status. Ultimate goals were to reduce foot wounds in diabetes patients, conserve financial resources for the organization, and provide a unique view of patients' perceptions of the limitations of diabetic foot problems.

The current study evaluated the effectiveness of nursing interventions to prevent life- and limb-threatening complications of diabetes. The specific aims were to:

1. Measure the effectiveness of a nurse-managed diabetes foot clinic's ability to reduce wound rates among patients with diabetes.
2. Measure the impact of a nurse-managed diabetes foot clinic's ability to improve the health status of patients with diabetes.
3. Measure the cost-effectiveness of a nurse-managed diabetes foot clinic.

Research Questions

The directional hypothesis pursued by the research team was that implementing a nurse-managed diabetes foot clinic would benefit patients and nursing practice by improving patient health and reducing overall health care costs. This hypothesis and study's aims generated three questions to be addressed by the research:

1. Does a nurse-managed diabetes-foot clinic reduce wound rates among patients with diabetes?
2. Does a nurse-managed diabetes-foot clinic improve the health status of patients with diabetes?
3. Does a nurse-managed diabetes-foot clinic reduce health care costs for patients with diabetes?

Theoretical Framework

The Quality Health Outcomes Model (Figure 1, Mitchell, Ferketich, & Jennings, 1998) presents the concept of quality outcomes as a dynamic, nonlinear model. It recognizes the importance of feedback throughout the structural components of health care, the interventions of care, and the influence of the client. No direct relationship exists between interventions and outcomes; interventions indirectly influence outcomes through system and/or client characteristics (Mitchell, Ferketich, & Jennings, 1998). In other words, client and system characteristics mediate the effect of interventions on outcomes.

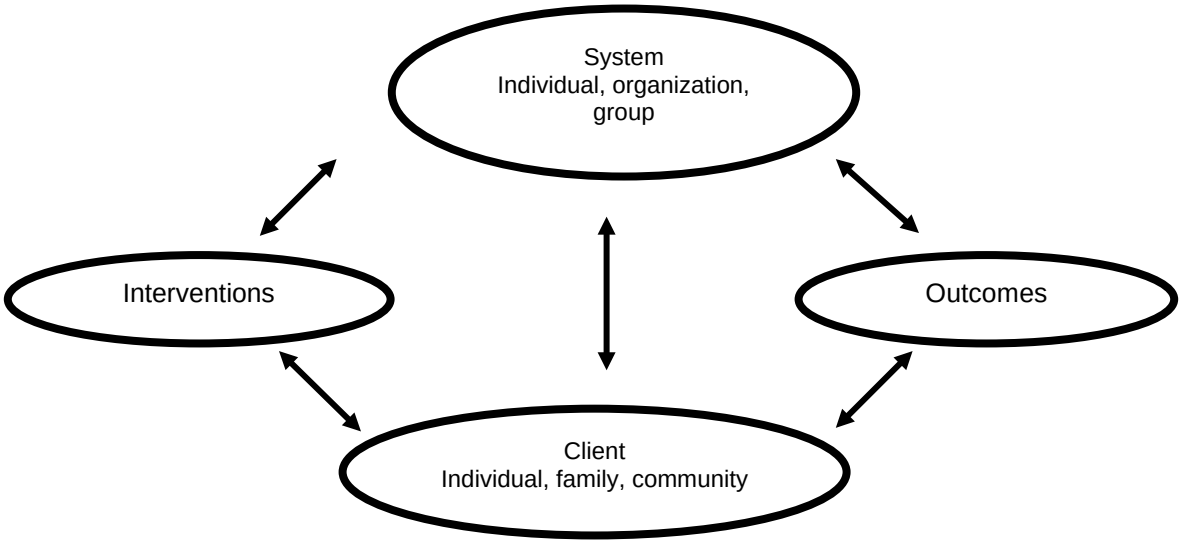


Figure 1. Quality Health Outcomes Model (Mitchell, Ferketich, & Jennings, 1998).

All four domains of the Quality Health Outcomes Model support this study. The framework helps describe what is observed and measured, explains various relationships, and tests which variables create the best outcomes for participants enrolled in the program. Elements of the model are determinants of health (the "health care system," the "individual," "organizations," and "groups"), which are acted upon by "interventions." These interventions affect consumers of health care ("client," "individual," "family," and "community") to produce health outcomes of varying qualities.

The desired outcome in this study was prevention of diabetic foot wounds, which may lead to foot or leg amputation. Preventing these wounds by interventions of preventive foot care can reduce the costs of health care because the average cost to heal one diabetic foot ulcer is $7,000–$47,000, and the average cost of an amputation is $23,000–$513,000 depending on the level of the amputation (Wu & Armstrong, 2006).

Given the number of patients with diabetes enrolled at Brooke Army Medical Center (2,667), and the incidence of foot wounds in people with diabetes, it can be seen that approximately 80 patients per year are at risk of losing a toe or lower extremity at a total cost exceeding $5 million, including podiatry referral costs. Approximately 1% of these beneficiaries are active duty soldiers. Thus, the outcome of reduced foot lesions and reduced amputations may save the health care system considerable money in addition to maintaining quality of life for the patients and their families and keeping a member of the community productive to contribute to society, thus contributing to the military mission.

VI. RESEARCH PLAN

Framework

The Quality Health Outcomes Model (Mitchell, Ferketich, & Jennings, 1998). serves as the conceptual framework for this study. *System characteristics* are defined as the traditional structure and process elements (i.e., ownership, staff mix, and technology) (Donabedian, 1980). For this study, we measured such relatively stable characteristics by collecting data from the control group of patients who did not receive care from the nurse-managed diabetes foot clinic; rather, they received the usual standard of care provided to diabetes patients at the medical center.

Interventions include clinical processes with indirect effects. The study's intervention was implementation of the nurse-managed clinic to coordinate and render care, provide patient education, and initiate wound-prevention principles.

The inclusion of *client characteristics* is needed to account for variations in patient health status. Severity of illness, risk factors, and demographics influence outcomes of care and were measured through clinical assessment and patient report questionnaires. Variables of specific interest included foot classification in terms of risk level (degree of peripheral neuropathy and foot deformity), the number of co-morbid conditions, and demographic information.

Measuring health status and cost *outcomes* is the first step in assessing the patient perspective and determining the consequences of health care (Kane, 1997). The outcome variables of interest are measurement of (1) the incidence and prevalence of foot wounds 12 months after the intervention, (2) the change in health status as perceived by patients before and after interventions, and (3) costs to the organization of admissions, clinic and emergency room visits, pharmaceuticals, surgeries, and wound therapies.

Design

A controlled, repeated-measures, two-group experimental design was used to measure the impact of a nurse-managed diabetes foot clinic on wound rates, health care costs, and changes in health status. This research design was chosen because:

1. Previous studies of foot wound prevention in patients with diabetes have used primarily non-experimental or quasi-experimental designs. Thus, using an experimental design increased the reliability of the knowledge generated.
2. Clinical trials are appropriate when testing an innovative treatment. Randomly assigning participants to treatment and control groups controls extraneous variables when measuring outcomes.
3. Patients with diabetes currently receive a variety of foot care interventions in several settings at BAMC, by several types of providers, with little measurement of outcomes. This study will fill a gap in the generation of outcomes data.
4. An experimental design requires standardization of care with subsequent measurements of outcomes to allow hypotheses testing and the study of relationships between variables (Polit & Beck, 2006).

This design minimizes threats to statistical conclusion validity, internal validity, construct validity, and external validity, respectively, by (a) conducting a power analysis *a priori* in order to reduce type II error and standardizing the implementation of the intervention; (b) randomly assigning participants to the control and experimental groups and establishing inter-rater reliability of intervention team members minimizes extraneous variables; (c) having a clear definition of all the variables and selecting measurements with established reliability and validity; and (d) offering participation to all patients with diabetes, making the study attractive to

the members of both the control and the experimental group, and by using different clinical settings for data collection (Sidani, 2002).

Sampling Plan

At the time of the study, there were 2,667 patients with diabetes enrolled in TRICARE at Brooke Army Medical Center (BAMC) as confirmed with the Military Health System Population Health Portal (MHS Portal, 2004). The target population for this study was patients with the diagnosis of diabetes for 5 years or more. Research shows that most people with type 2 diabetes (85% of all people with diabetes) have had diabetes for at least 10 years prior to diagnosis. Neuropathy occurs in diabetic patients primarily after 15 years and 50% of people with type 2 diabetes have neuropathy and at-risk feet (Apelqvist, Bakker, von Houtum, Nabuurs-Franssen, & Schaper, 2000; Mayfield, Reiber, Sanders, Janisse, & Pogach, 1998). Neuropathy is the primary predictor or risk factor for ulceration in patients with diabetes.

Foot clinics in the Family and Internal Medicine Clinics were started as a pilot to this study and enrolled ~1,300 patients who continue to be followed by the clinics and were therefore ineligible for enrollment into this study. It was estimated that about 30% of patients with diabetes at BAMC are at high-risk for foot disease, or 390 of the 1,300 eligible for the study. Patients with very-high-risk foot disease were estimated at 10% (130 of 1,300 eligible for the study at BAMC). A prediction was made that 20% of the 520 patients eligible for this study would consent, thus the study would enroll only 104 subjects instead of the intended sample of 250.

Eligiblity Criteria

Patients were considered eligible for this study if they were 18 years or older, had a diagnosis of diabetes for 5 years or more (patient self-report), were classified as at high or very-

high risk for ulceration, and were able to read English. Potential participants were excluded if they had Charcot foot (a condition in which the bones of the foot collapse, causing challenging foot deformities and unpredictable inflammation), were enrolled in the Family Medicine Service Foot Clinic, or had diabetes for less than 5 years.

All patients with diabetes identified by a search on the computerized medical record system and/or referred by physicians, were invited to be screened, with 254 enrollees at BAMC who agreed to be screened and 128 who were enrolled into the study. Participants needed to be able to commit to clinic visits over the course of 12 months, varying from every week to once every 3 months, depending on whether the participant was in the experimental group, and the foot classification. A patient presenting with a foot ulcer at the initial visit was eligible for the study.

Effect Size

The effect size, based upon the literature claim of 45%–80% reduction (CDC, 2003) was set at a 50% reduction in ulceration rates for both the very-high- and high-risk groups (Litzelman et al., 1993). The very-high-risk group was assumed to have a wound rate of 60% annually, and the high-risk group, a rate of 40%. The proposed total sample size was 250 (90 for the very-high-risk group and 160 for the high-risk group), allowing for an attrition rate of 20%. The sample size of 250 was sufficient to detect a small-to-moderate effect size (0.3) in all additional analyses. Exhausting all pools of candidates at the medical center resulted in a total enrollment of only 128 participants and only 126 completed data collection. A power analysis was redone in September 2005 based on the actual 22% wound rate observed during the prior 6 months. With alpha at 0.05 and power at 0.8, it was determined that 120 subjects (60 per group) would be sufficient to answer the research questions. To allow for attrition, 128 subjects were enrolled by

December 2005. This represented all willing participants enrolled in BAMC with diabetes who qualified for the study.

Recruitment

The research team recruited patients from six different TRICARE clinics: the Internal Medicine Clinic, the Family Medicine Services Clinic, the Orthopedic Clinic, the Endocrinology Clinic, the Troop Medical Clinic, and the Brace Shop. Rolling recruitment enrolled participants as they presented to the clinic and each participant was followed for a 12-month data-collection period unless participants chose to withdraw.

To publicize the study, researchers visited each of the clinics on a rotating basis to access potential participants. Principal care providers (PCPs) in each clinic were briefed about the study and encouraged to refer eligible patients to the study. The research team developed a promotional brochure and business card–sized magnets for distribution to patients, providers, and hospital personnel.

Potential participants were screened for eligibility criteria, received a briefing on the study, and asked to volunteer. The team obtained written, informed consent for all participants. Researchers reviewed the consent form with the participant and answered any questions. Participants received a copy of the consent form, which included points of contact. A Health-Information Portability Protection Act information form was also signed and a copy provided to participants.

Randomization

The study used a stratified random-sampling approach. When subjects presented for informed consent, they were screened for foot category according to the criteria of the Veteran Affairs Puget Sound Health Care System, Seattle Division (Ahroni, 2003). To randomize eligible

participants, the researcher drew a card from one of two boxes (corresponding to high-risk or very-high-risk categorization), and assigned the participant to the control group (for cards marked with the number 1) or the experimental intervention group (cards marked with the number 2). The two groups of 20 cards each were reshuffled three times and reused as exhausted until the desired number of subjects was achieved. Operating with a limited deck of 20 cards at a time facilitated the even assignment of subjects to the control group and the intervention groups as the study progressed.

Tracking

Each participant, whether part of the control group or the experimental group, was assigned a participant identification code, a four-digit number used consistently with all data collection tools. The code specified whether a participant was in the experimental or control group and facilitated tracking of the total number of participants and visits.

The control group was assigned quarterly appointments at the nurse-managed diabetes foot clinic for foot evaluation and wound classification. Control group participants exhibiting foot problems were referred to their primary care provider. Experimental group members were assigned appointments based on their foot evaluation classification. The number of visits for these varied from every week to every 3 months and was dependent upon reassessment.

Description of Intervention

Pilot Study

The principal investigator of the current study, a nurse practitioner, conducted a pilot study to determine the need for, and barriers to, preventive foot care at BAMC. The clinic enrolled 600 of the 4,400 patients with diabetes at BAMC over a period of 1 year. Primary care

providers in the clinics referred patients to the nurse practitioner for education and foot care. The 600 patients were classified based on risk assessment; high-risk patients were seen every 1 to 2 months, moderate and intermediate risk patients were rescheduled every 4 to 6 months, respectively, and low-risk patients were scheduled to return yearly. Based on the risk assessment of the 600 patients, 10% required monthly examinations, 20% needed to be seen biannually, and 20% needed to be seen quarterly. The remainder of the patients was classified as low risk and qualified for yearly evaluation.

Patient data were maintained in a separate Access® database with alert recognition when appointments were due based on foot classification. Patients were notified in advance of their appointments to ensure limited missed appointments. The patient's primary care provider was notified of the risk level of the patient, the care provided, any problems present, and recommendations for referral as needed. Patients received education, assessment, and treatment.

The pilot program was very successful over the course of 3 years and attrition was less than 10%, with many patients still receiving care in these clinics. Although data were not collected in the first year on outcomes for glucose control or wound prevention, only three patients developed foot wounds that required specialty debridement or surgical intervention, and two patients had single toe amputations, one of whom presented with a black and infected toe. Primary care providers reported better glucose control among patients referred to the pilot-study foot clinic.

The Nurse-Managed Diabetes Foot Clinic

Patient Education. Every participant in the study, whether in the control group or the experimental group, received foot care education at their first appointment for evaluation and

care. The foot education reviewed the basics of diabetes (glucose control, benefits of diet and exercise, medications), common foot problems, and the basics of good footwear. Patient education was reinforced at subsequent visits.

Foot Evaluation. Every participant received an initial foot evaluation (see foot assessment form in Appendix F). The foot evaluation included assessment of peripheral vascular disease/venous stasis (dorsalis pedis and posterior tibialis), sensation in the foot, gait, lesions, shoe wear fit, and any foot deformities. Foot assessment was based on the Diabetes Foot Assessment and Treatment Guideline (Rith-Najarian & Reiber, 2000; Foster & Edmonds, 2001) and an Ulcer and Ischemia Classification (Wagner, 1981). This process was repeated at each visit. A brief history of the disease process was taken, including current medications and previous diabetes education. Laboratory values (lipids, glycosylated hemoglobin A1C, and urine microalbumin) were reviewed for anything that required the PCM's attention.

Treatment. Experimental group treatment was based on the *Diabetes Foot Assessment and Treatment Guideline* (Rith-Najarian & Reiber, 2000) and included shaving calluses, trimming nails, debridement of corns, and treatment of any wounds with referral if needed; and prescribing emollients/lotions, antifungals/antibiotics, shoe inserts, and special footwear as necessary. Participants were referred to the department of surgery's wound clinic or the orthopedics clinic's problem foot clinic for more extensive therapy, as indicated by foot and ulcer assessments. PCPs were informed of the treatment plan and any referrals.

Data Collection

Interrater Reliability

To establish inter-rater reliability, all nurse data collectors were trained in the Veterans Affairs Puget Sound Health Care System, Seattle Division (Ahroni, 2003) foot classification

system after the manner of Wagner (1981) by Dr. Gilcreast. The course provided didactic instruction, pictures, and discussion of classifying diabetic feet into the four categories: low risk, moderate risk, high risk, and very high risk. The data collection nurses attended an active nurse-run diabetic foot clinic operated by Dr. Gilcreast to observe foot assessment/care and reinforce the principles learned. Following instruction, Dr. Gilcreast observed the research nurses classifying 10 patients (ineligible as subjects in the study). Each patient was examined by three different nurses in the nurse-managed diabetes foot clinic. The results of the classifications were compared using Pearson's product moment statistics to determine the reliability obtained by each group of three nurses. The criterion was set at $r = 0.8$. This criterion was achieved on the first iteration.

Instruments

Patient Surveys

All participants completed two surveys (a demographic survey, the SF-36 Health Survey, version 2) upon enrollment (Appendix F). At the end of 12 months, participants completed the SF-36 Health Survey for a second time, a patient satisfaction questionnaire, and the Palo Alto Veterans Affairs Health Care Usage Questionnaire, (Wagner, 2003). The demographics survey assessed age, gender, marital status, ethnic group, income level, education, years with diabetes, medications to control diabetes, and co-morbidities. The SF-36 assessed the participants' views of their health status. The Palo Alto Veterans Affairs Health Care Usage Questionnaire assessed total health care usage over the year the participant was enrolled in the study.

SF-36 Health Survey version 2

The widely used SF-36 Health Survey v.2 (SF-36; Ware, Snow, Kosinski, & Gandek, 1993) was constructed to represent multi-dimensional health concepts and designed for use in clinical practice, research, health policy evaluation, and general population survey. The SF-36 provides a self-administered global measurement of health status using 36 general health questions. It also questions the patient's perception of his/her health status and is able to represent multi-dimensional health concepts, inclusive of mobility measurements.

The SF-36, revised, Version 2, measures eight concepts, each with reported reliability and internal consistency (IC): physical functioning (R = 0.94; IC = 0.80); role-physical (R = 0.94; IC = 0.79); role-emotional (R = 0.93; IC = 0.53); bodily pain (R = 0.85; IC = 0.76); general health perceptions (R = 0.83; IC = 0.69); vitality (R = 0.85; IC = 0.68); social functioning (R = 0.88; IC = 0.78); and mental health (R = 0.85; IC = 0.50). Scoring involves several steps: (a) enter data, (b) re-code data on a scale of 0 to100, (c) transform individual items into eight subscales, (d) obtain the *z*-score for each of the eight subscales, (e) compute aggregate scores for two subscales (physical and mental component scores), (f) transform aggregate scores to norm-based scoring based on the 1998 U.S. population values, and (g) perform scoring checks (Ware, Kosinski & Dewey, 2000[

Wound Incidence and Prevalence

Each participant's appointment in the nurse-managed foot clinic included examination for foot wounds (occurring below the ankle), signs of pressure from selected shoes, athlete's foot, nail fungus, nail length/shape, calluses or corns, treatment, and education.

Semmes-Weinstein Monofilament

Several studies have validated the Semmes-Weinstein Monofilament (SWM) as the best choice for screening for clinically significant neuropathy (Armstrong, 2000; Mayfield & Sugarman, 2000). The SWM is portable, inexpensive, painless, easy to administer, acceptable to patients, and provides good prediction of the risk for wounds and amputation. Compared to other instruments, the SWM was noted to be the most sensitive to loss of sensation in predicting wounds, with an odds ratio of 2.9 for predicting LEA when compared to vibratory pressure instruments (Armstrong, 2000; Mayfield & Sugarman).

Health Care Costs

BAMC tracks patient visits and inpatient stays in its computer systems. Outpatient visits, prescription drug fills, consults, treatments, and lab and x-ray testing are tracked in the Combined Health Care System. Inpatient stays are maintained in the Clinical Information System. Results from both systems were provided to the health care providers. Aggregate data pulls were accomplished by the Health Plans Management Department. It was difficult to access this information throughout the study because the original health care financial analyst ended his association with the grant and BAMC. Therefore, a health care economist consultant was hired and designed a questionnaire to obtain this information by patient report. He also double checked the data provided by the statistical consultant for consistency with his findings. All participants were reliable historians. The health care economist used BAMC reported charges for the services and compared them to prevailing Medicare charges.

Data Analysis Plan

Data were entered as they were collected into the Statistical Package for the Social Sciences (SPSS)® and were cleaned periodically. Descriptive statistics comprise frequencies and percentages for categorical variables and means, standard deviations, skewness, and kurtoses for continuous variables. Exploratory data analyses (boxplots, quantile-quantile plots, density plots, and resistant estimators of location and spread) were used to review the distributions of the variables and distributional anomalies such as non-normality of data, heterogeneity of variance, ceiling or floor effects, potential outliers, and the need for transformations were identified. Transformations were based on visual inspection and Box-Cox procedures. Bivariate exploratory analyses were conducted with matrix scatter plots supplemented with linear regressions to reveal linear and nonlinear relationships between variables. Data exhibiting unusual properties were reviewed for validity and corrected as necessary. Legitimate extreme values were noted, but not removed from the data set.

All statistical analyses are based on the intention-to-treat approach: Each subject was analyzed according to the group to which he/she was assigned regardless of whether he/she actually received treatment, standard care, or supplemental care external to the study. The two continuous dependent variables (health care costs and change in health status) were subjected to a two-treatment-group by two-risk-group by four-measurement-occasions multivariate analysis of covariance. The additional covariates were influence of pre-existing conditions, classification of foot risk, years since diabetes diagnosis, the pre-intervention measurement of the health status, and the number of co-morbid conditions.

All multivariate analyses were supplemented with univariate analyses using the SPSS. Wound rates and rates of amputation (there were none) were analyzed by multiple logistic

regression or multiple Poisson regression. Rates of positive foot care outcomes were analyzed by multiple logistic regression.

Patterns of missing data were examined through the exploratory data analysis and logistic regression (missing/not missing being the dependent variable) to assess whether or not "missingness" was ignorable. The team paid careful attention to the possible causes of dropout to determine if the dropout rates, even if not statistically different between the two groups, could be caused by treatment intervention or standard care in the control. For ignorable data, the statistical methods mentioned above were modified (maximum likelihood approaches or data augmentation) to accommodate missing data.

All analyses were followed by diagnostic analyses to assess the appropriateness of the model and the possible presence of data points with undue influence or leverage. Such points were removed and the analyses re-run.

Cost of the Intervention

Data were cleaned and analyzed in Stata version 9.2®. Dichotomous variables were recoded so that 1 = yes and 0 = no. The health care economist replicated the consulting statistician's work for efficacy models to assure consistency in data. For lesions, the health care economist used a conditional logit model whereas the consulting statistician used repeated-measures ANOVA. The health care economist ran a number of models comparing visit 1 with visit 5, or the last visit, if visit 5 was missing. This had little effect on the results despite the larger sample size.

Assessing the cost of the intervention was the first step in addressing the economic aims. Aim 1 investigated whether the intervention resulted in less health care use and if the reduced

health care usage would pay for the intervention. Aim 2 was broader than aim 1 and compared the costs of the intervention relative to changes in effectiveness. Both these aims are discussed in detail below. All costs were standardized to 2006.

The cost of the intervention was calculated using Medicare payments based on Common Procedure Terminology (CPT) Codes, which were tracked for each visit. Costs per visit were summarized using these codes, and then the total cost per participant was calculated. The CPT costs included the APC cost for provision of care in a hospital (Phibbs, Bhandari, Yu, & Barnett, 2003). Participants received care categorized by eight CPT codes, which are summarized in Table 1.

The intervention also tracked the time spent with each participant. This time estimate confirmed the CPT costs. To translate time into a cost, the national average wage for a registered nurse of $28.71 (2006 dollars) (Bureau of Labor Statistics, 2007) was used. The total cost was multiplied by 130% to adjust for the hospital's indirect costs. Estimating costs based on time can significantly underestimate the total costs of the intervention because this method assumes that all of the nurse's time is spent providing care to patients (Wagner, Engelstad, McPhee, & Pasick, 2007). In reality, nurses have other duties (e.g., meetings, training, maintaining patient charts). Therefore, costs estimated from CPT codes are preferred over estimating costs from time reports. As expected, there was a positive correlation between CPT code costs and time-based costs, however, the correlation was only moderate (0.22), suggesting that time was not always an accurate predictor of the amount of services provided to a participant.

Table 1.

Cost per Common Procedure Terminology (CPT) Code

CPT code	Description	Estimated Cost (in 2006 $$)*
11055	Trimming of 1 callus	66.11
11056	Trimming of 2–4 calluses	76.34
11057	Trimming of more than 4 calluses	108.44
11719	Trimming toenails (regular)	48.33
11720	Debriding 1–5 hypertrophic toenails	56.66
11721	Debriding 6–10 hypertrophic toenails	69.17
98960	Patient Education (non-physician)	36.18
99499	Evaluation and Management	69.17

*Costs were based on estimated Medicare payments and include provider and facility components.

Health Care Utilization and Cost

At each visit, participants were asked about health care use since their last visit (generally every 3–4 months). Patients reported using care in Department of Defense, Department of Veterans Affairs, and commercial hospitals. There were no differences between the control and experimental group in healthcare utilization by facility ownership. Therefore, the participants reported utilization was combined with national average (Medicare) cost data for 2006. (Phibbs et al., 2003; Wagner, Chen, & Barnett, 2003; Yu, Wagner, Chen, & Barnett, 2003). For unit costs, the amounts used were $2,500 per day for inpatient care, $192 per outpatient general medicine visit, $143 per outpatient mental health visit, $133 per outpatient physical therapy visit,

$49 per outpatient chiropractic visit, and $446 per home-based outpatient visit. Costs were calculated for durable medical equipment, namely inserts ($25.33) and shoes ($213). The outpatient, inpatient, and total costs per participant were calculated. Negative binomial models with robust standard errors were used to test for differences in usage between groups (Cameron & Trivedi, 1998). Cost differences between groups were tested using general linear models with a log link and a gamma distribution. Costs were also examined using ordinary least squares.

Utilities

To date, the quality-adjusted life year (QALY) model is the preferred metric for estimating the health effects in an economic analysis (Gold, Siegel, Russell, & Weinstein, 1996). QALYs incorporate both duration of life and quality of life, such that each life year gained is multiplied by a quality weight that reflects the individual's quality of life in the health state for that year. Utilities, measured on a scale from zero (death) to one (perfect health), can be used as the quality weights for given health states (Goldstein & Tsevat, 2003).

QALYs take into account preferences for different health states and the amount of time people spend in different states of health. Therefore QALYs reflect a person's health path. Interventions may result in changes in health paths. By aggregating QALYs for people in the intervention and control groups, one can develop an estimate of the incremental health effect associated with the intervention. This provides information that can be used in the cost-effectiveness analysis.

Participants in the study completed the SF-36 Health Status Survey. The Brazier scoring method was used to calculate the SF-6D utility score (Brazier, Roberts, & Deverill, 2002). The

utility score and the time the participants spent in the trial were combined to estimate QALYs. Estimating lifetime QALYs was beyond the scope of this study.

Cost Offset Analysis

Whether the intervention reduced health care use, thereby saving money for the health care provider was examined. The cost offset model is calculated as shown in equation 1. Total cost of the intervention (Int_{cost}) was estimated and compared to the cost of subsequent health care usage (HC_{cost}). Whether the experimental and control groups differed in costs was then tested. For the control group, the intervention cost is usual care. For the experimental group, the intervention cost is usual care plus the added cost of the nurse-managed foot clinic.

Equation 1:
$$\text{Cost offset} = (Int_{cost} + HC_{cost})_{\exp} - (Int_{cost} + HC_{cost})_{control} \quad (1)$$

Cost-Effectiveness Analysis

The incremental cost per quality-adjusted life year was calculated, as shown in equation 2, using the societal perspective. All costs, irrespective of who bears them during the study, were included (Gold et al., 1996). This analysis included patient incurred costs, whereas the cost-offset model does not. Patient-time costs, valued at the federal minimum wage for 2006 ($5.15 per hour) were estimated. Co-payment amounts were not included because those data were not available. Extending the analysis to include lifetime costs and benefits was beyond the scope of the study.

Equation 2:
$$\text{Incremental C/E Ratio} = \frac{C_{\exp} - C_{control}}{E_{\exp} - E_{control}} \quad (2)$$

Bootstrapping with 1,000 replications enabled calculation of 95% confidence intervals for the incremental cost-effectiveness ratio (Efron & Tibshirani, 1994). The bootstrap enabled calculation of non-parametric confidence intervals without making assumptions about the distributions of the data.

Subgroup Effects

Cost-offset models and CEA models for different subgroups were constructed. To assess whether there were subgroup effects by disease severity, the following states were compared: (1) HbA1c < 7 versus HbA1c ≥ 7; (2) neuropathy risk factor category 3 versus category 4; and (3) years with diabetes < 10 versus ≥ 10. Whether there was a gender effect was also assessed as was whether any health care cost differences exist looking at only diabetes-related health care usage. Finally, because many interventions face a start-up period, we assessed whether there were any differences between participants in the first half of the trial and those seen in the second half.

VII. Data Analysis

Summary of Data

Demographic Results

Of the 128 subjects enrolled, data were analyzed on only 126 (see Tables 2 and 3). One subject with Charcot foot was erroneously enrolled and did not qualify. Another withdrew after the first visit. One participant who dropped out was active duty military and transferred to another duty station after the first visit. Both participants were treatment (Tx) group members, leaving 62 in that group.

Table 2.

Recruitment and Retention

	Originally Projected	**Actual Number**
# subjects available	3,600	2,667
# subjects contacted	1,494	1,494
# subjects screened	500	254
# subjects refused	250	126
# subjects consented	250	128

	Treatment	**Control**	**Treatment**	**Control**
# subjects enrolled	125	125	62	64

# subjects dropped out	25	25	12 (19.3%)	23 (35.9%)
# subjects completed intervention	100	100	50	41

Subjects with high-risk feet made up 59% of the sample [Control (C) = 55%, Tx = 63%] and those with very-high-risk feet 41% (C = 45%, Tx = 37%). This is a slightly higher percentage of very-high-risk feet than expected. We predicted 67% high-risk feet and 33% very-high-risk feet.

The sample was 60% male (C = 63%, Tx = 58%) and 40% female (C = 37%, Tx = 42%). This is typical of an aging group (*M* = 63.2 y) in a military health care facility. The treatment group (*M* = 65 y) was significantly older than the control group (*M* = 62 y; *p* = .003).

Ethnicities claimed were 50% Caucasian (equal in groups), 23% African American (C = 19%, Tx = 27%), 17% Hispanic-Latino (C = 16%, Tx = 19%), 9% Other (C = 15%, Tx = 3%). One subject chose not to report ethnicity. Most participants were married (C = 89%, Tx = 81%).

Educational levels of participants were high school or less, 27% (C = 23%; Tx = 32%); some college, 49% (C = 52%, Tx = 45%); college graduate 14% (C = 16%, Tx = 13%); and master's degree or higher, 10% (C = 9%, Tx = 10%).

The groups had no significant difference in duration of diabetes diagnosis (C, *M* = 12 y, Tx, *M* = 13 y). Fifty-seven percent of subjects took oral hypoglycemic medications and 33% took injected insulin. Many patients were on multiple medications to manage their diabetes. Risk factors other than foot-risk categories appeared evenly spread between the two groups. Risk factors may have been equalized by the Tx group being older and having more African Americans and Hispanics.

Table 3.

Sample Demographics

Parameter	**Entire Sample**	**Control**	**Intervention**
Foot wound risk:	126	64	62
High	74	35	39
Very high	52	29	23
Gender:			
Male	76	40	36
Female	50	24	26
Age:			
≤ 39 y	3	3	0
40–59 y	48	24	23
60–79 y	70	36	39
≥ 80 y	5	1	4
Ethnicity:			
Caucasian	63	32	31
African American	39	12	17
Hispanic	22	10	12
Asian American	4	3	1
Other	7	6	1

Educational level:			
≤ High school	35	23	32
Some college	62	52	45
College graduate (baccalaureate)	18	16	13
Advanced degree	11	9	10
Marital status:			
Married	107	57	50
Single	9	4	5
Widow/Widower	10	3	7
Income level:			
≤ $19,999	16	7	9
$20,000–$39,999	22	9	13
$40,000–$59,999	37	20	17
$60,000–$79,999	29	14	15
$80,000–$99,999	14	8	6
≥ $100,000	8	6	2
Anti-glycemic medications*			
None	16	11	5
Sulfonylurea	66	39	27
Meglitinide	0	0	0
Metformin	72	35	37
Glucosidase inhibitor	1	1	0
Thizoladinediones	40	19	21

Insulin	41	19	22

*Some patients were on multiple meds.

Results of Study Aims

Question 1: Does a nurse-managed diabetes foot clinic reduce wound rates among patients with diabetes?

Table 4 summarizes analyses of variance (ANOVAs) on four physiologic outcomes. Only the interaction terms are shown. A single effect—lesion prevalence—showed statistical significance. From Cohen's (1988) rough guidelines, the actual effect size is close to the medium category. Figure 2 is a graphical depiction of this significant interaction. The control group showed a substantial increase in prevalence from the first to the fifth visit, whereas the Treatment group prevalence declined.

Table 4.

Repeated Measures ANOVAs on Physiologic Outcome Measures

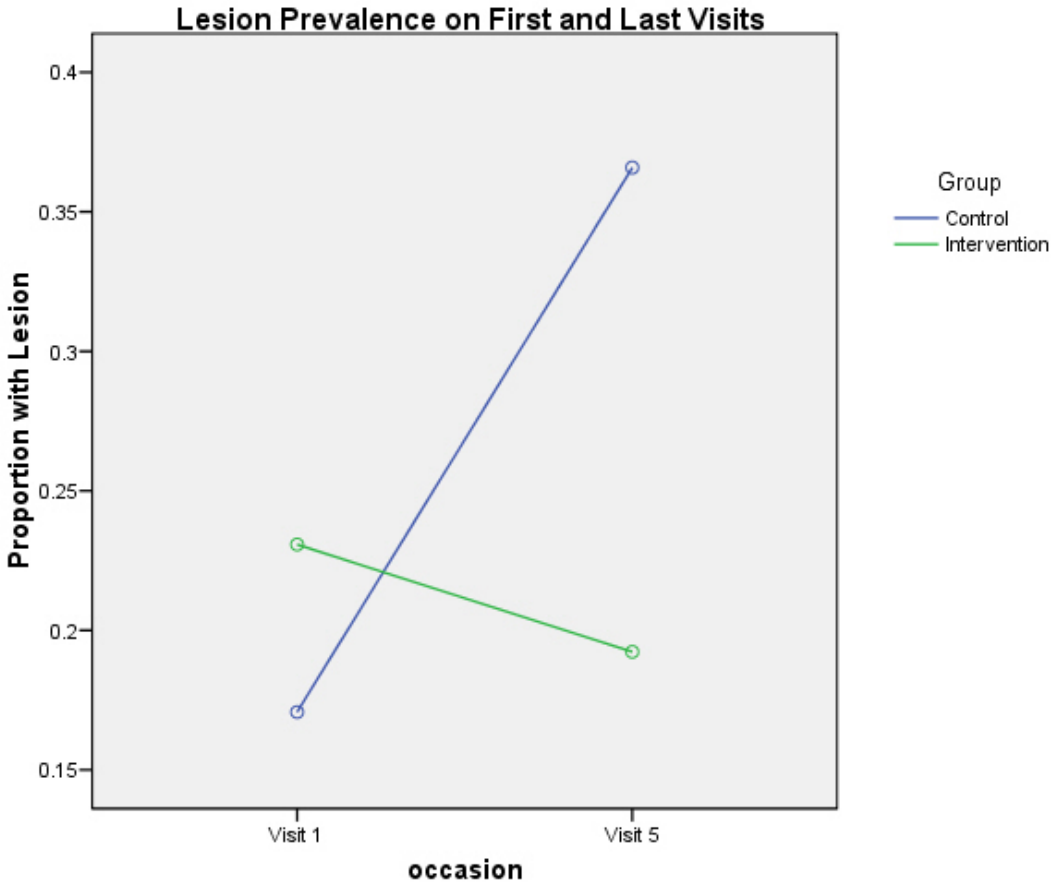
Measure	***SS***	***df***	***MS***	***F***	***p***	***E.S.****
Lesion Prevalence	.625	1	.625	4.672	.033**	.049
Monofilament Right	.677	1	.677	.404	.527	.005
Monofilament Left	1.084	1	1.084	.612	.781	.007
HgA1c	.279	1	.279	.763	.389	.025

*Effect size eta squared (η^2) represents proportions of variance explained by term.

**Statistically significant

Figure 2:

Differential change on wound prevalence.



Question 2: Does a nurse-managed diabetes foot clinic improve the health status of patients with diabetes?

Table 5 summarizes the repeated measures analyses of variance (RM-ANOVAs) for the various subscales of the SF-36. Each RM-ANOVA followed the same 2 (Group) × 2 (Occasion) structure. The two groups were Control vs. Treatment, and the two occasions were visit 1 vs. visit 5. In such a repeated-measures ANOVA model, three effects are tested, but two—the main effects—are usually ignored. The group effect has little meaning because it ignores the separate

measurement occasions and averages across them. The occasion effect is muddled because it ignores the grouping structure and asks whether there are pre-to-post changes for the entire sample. It is the interaction term, which does no averaging of groups or occasions, that is the focus of such an analysis. The interaction asks the essential question, "Did the two groups change differently over time?" Thus, Table 5 omits the tests of the main effects and includes only the important interaction terms.

From Table 5, none of the SF-36 scale scores were statistically significant. One might speculate that the study was underpowered to answer this question because sample sizes were not large enough. However, the effect sizes, which are independent of sample size, are also very small. In summary, the control and treatment groups did not show differential change between visit 1 and visit 5 on the quality-of-life outcome measures.

Table 5.

Repeated Measures ANOVAs on SF-36 Normed Scales

Measure	***SS***	***df***	***MS***	***F***	***p***	***E.S.****
Physical Function	.305	1	.305	.923	.339	.008
Role-Physical	.149	1	.149	.259	.612	.002
Bodily Pain	.031	1	.031	.078	.781	.001
General Health	.102	1	.102	.324	.570	.003
Vitality	.015	1	.015	.032	.858	< .001
Social Function	.073	1	.073	.110	.741	.001
Role-Emotional	.311	1	.311	.302	.584	.003
Mental Health	.577	1	.577	1.765	.187	.016

*Effect size is η^2 (eta squared), which represents the proportion of the variance explained by the tested term.

Question 3: Does a nurse-managed diabetes foot clinic reduce healthcare costs for patients with diabetes?

1) Did the intervention offset subsequent health care utilization, thereby saving money?
2) Was the intervention cost-effective compared to usual care?

As expected, there was a positive correlation between CPT code costs and time-based costs; however, the correlation was only moderate (0.22), suggesting that time was not always an accurate predictor of amount of services provided to the participant.

As shown in Table 6, participants in the treatment group had an average of 5.2 visits (range 1–8), whereas participants in the control group had 4.4 visits (range 1–8). Consistent with this finding, participants in the treatment arm averaged 244 minutes (*SD* = 30) of visit time compared to the control arm's average time of 201 minutes (*SD* = 30).

Table 6.

Number of Visits and Time Spent with Participants

	Experimental Group (n = 62)		Control Group (n = 64)		Total (n = 126)	
Variable	*M*	*SD*	*M*	*SD*	*M*	*SD*
Number of visits	5.2	1.2	4.4	1.0	4.8	1.1
Time spent with participant (minutes)	243.9	70.8	160.3	38.5	201.4	70.4
Days in the study	351.1	74.2	333.0	86.2	341.9	80.7

The average participant was in the study for almost a year (340 days), as determined by the first visit and the last visit date. Three participants left the study after the first day and one was in the study for 524 days (1.4 years).

Cost of the Intervention

Table 7 shows that the average cost per participant in the treatment group was $661, which was $312 more than the average cost per participant in the control group ($349). Variability in costs was also higher in the treatment group (*SD* = $211) than in the control group (*SD* = $93), as shown in Figure 3. The mean difference in costs between the two groups was highly statistically significant, after controlling for the differences in variability (heteroskedasticity) using robust standard errors (*t* stat = 10.68, $p < .0001$).

Table 7.

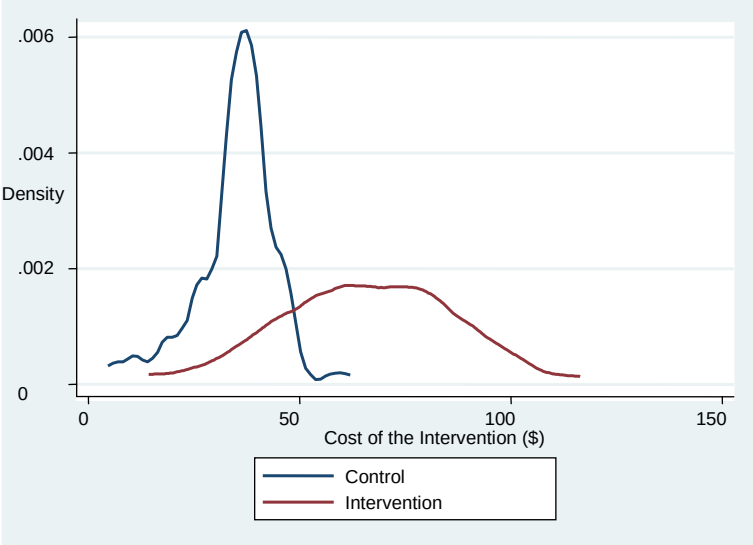
Intervention Costs

	M	Median	*SD*
Experimental Group	$661	$675	$211
Control Group	$349	$365	$93
Difference*	$312		

The difference was significantly different (*t* = 10.68, $p < .0001$, two-tailed test).

Figure 3:

Visual Representation of the Distribution of Intervention Costs for the Control (Usual Care) Group and Treatment Group



Note: Graph shows the distribution density

Health Care Utilization and Cost

Table 8 shows the cost of health care used by the participants. Approximately 10% of the participants reported being hospitalized after enrolling in the study; but these hospitalizations were unrelated to their feet (back surgery, bladder surgery, knee replacement). For those who reported being hospitalized, the median length of stay was 4 days (range 1–20 days). Outpatient care was more common than inpatient care, as expected, with the average person reporting eight outpatient visits. Although the control group reported fewer inpatient days than the treatment group, this difference was not significant. No statistically significant differences in utilization were found between the treatment and control groups, in part because the difference was small, the sample size was small and the variability in costs was high.

Table 8.

Health Care Utilization and Costs

	Experimental Group (n = 62)		Control Group (n = 64)		Total (N = 126)	
	M	*SD*	*M*	*SD*	*M*	*SD*
Hospitalized (proportion)	0.1	0.3	0.1	0.3	0.1	0.3
Length of stay (if hospitalized)	5.2	7.4	6.3	5.0	5.8	6.0
Total number of outpatient visits	8.3	10.2	7.8	10.2	8.0	10.2
Inpatient Costs ($)	1,250.0	6,556.0	1,718.8	6,250.0	1,488.1	6,381.1
Outpatient Costs ($)	1,529.1	1,941.3	1,382.1	1,729.7	1,454.5	1,830.9
DME Costs ($)	24.8	56.0	14.5	64.3	19.6	60.4
Total Costs ($)	2,803.9	7,281.1	3,115.4	7,210.8	2,962.1	7,218.1

On average, participants' health care cost was $2,962 (*SD* = $7,218). As is common with cost data, the range was very large ($0–$53,870) and the distribution was skewed. Health care costs were evenly distributed between inpatient and outpatient costs. The mean total cost of health care use was $2,803 for the treatment and $3,115 for the control group. Although costs averaged $312 less in the treatment group, this difference was not significant because of the large variance. Consequently, no significant differences in costs were seen between the experimental and control groups. The results were robust to the choice of statistical model and the presence of outliers, identified with Cook's distance. People in the treatment group reported slightly higher amounts of diabetic-related health care utilization. However, these differences were not statistically significant in multivariate models (results not shown).

Effectiveness

Quality adjusted life year (QALYs), were calculated by multiplying change in utility scores by days in study, normalized to years. Table 9 shows that the average within-person utility change was very small and not clinically meaningful. The treatment group's average utility score decreased (worsened) by 0.01, on a 0–1 scale, whereas the control group's average utility increased (improved) by that same amount. These changes could easily reflect "noise."

Table 9.

Utility and Quality Adjusted Life Years

	Experimental Group		**Control Group**		**Total**	
	M	***SD***	***M***	***SD***	***M***	***SD***
Utility change	–0.01	0.09	0.01	0.10	0.00	0.09
Days in study	351.08	74.20	333.02	86.21	341.90	80.72
QALY	–0.01	0.09	0.01	0.10	0.00	0.10

Aim 1: Cost Offset

As expected, adding the nurse education program yielded significantly higher costs per participant in the treatment group than in the control group (see Table 10). The treatment group used less health care than the control group, but this difference was not significant. The total cost (intervention cost plus health care costs) was $3,465 for the treatment group and $3,464 for the control group. This suggests that when combining the cost of the intervention and the cost of health care utilization, the intervention did not yield higher costs than the control group.

Conversely, the results suggest that the intervention did not save money, when factoring in the cost of the intervention.

Table 10.

Cost Offset for the Intervention

	Experimental (Avg. $)	**Control (Avg. $)**	**Difference (Avg. $)**
Intervention Cost	661.01	348.62	312.39
Health Care Costs	2803.87	3115.39	–311.52
Total Costs	3464.88	3464.01	0.87

Aim 2: Cost-Effectiveness Analysis

Comparing the treatment group to the control group showed a very small incremental cost (< $10; see Table 11). Table 11 also shows the incremental change in QALYs (–0.02). The incremental cost per quality adjusted life year was –$30.4 with a 95% confidence interval of (–$464321.7 to $270560.1), calculated using bootstrapping with 1,000 replications.

Table 11.

Incremental Cost per Quality Adjusted Life Year

	Experimental	Control	Difference
Intervention Cost	$661.01	$348.62	$312.39
Health Care Costs	$2,803.87	$3,115.39	–$311.52
Patient Costs	$20.94	$13.76	$7.18
Total Costs	$3,485.82	$3,477.77	$8.05
QALY	–0.01	0.01	–0.02
Incremental Cost per QALY	--	--	–$30.40*
95% CI			(–$464321.7, $270560.1)

*Computed with more precision than shown in table.

Subgroup Effects

The subgroup analysis showed no meaningful differences, with one exception. In each analysis, the control arm had slightly greater improvements (or smaller declines) in QALYs than the experimental group (see Table 12). The one notable difference was for people who had diabetes for 10 years or more. Those participants were significantly more expensive in the control group than in the experimental group. However, this difference was not statistically significant due to the large variance and small sample size.

Table 12.

Subgroup Effects

	Change in QALYs		Societal Costs ($)*		Provider Costs ($)**	
	Exp.	Control	Exp.	Control	Exp.	Control
Overall	–0.015	0.014	3,486	3,478	3,465	3,464
HbA1c < 7						
No	–0.008	0.013	4,387	4,332	4,409	4,345
Yes	–0.026	0.015	1,901	1,808	1,921	1,822
Diabetes neuropathy severity						
neuropathy with foot deformity/no hx ulcer	–0.009	0.032	2,970	3,244	2,989	3,258
neuropathy, hx of ulcer/amp. + foot deform.	–0.024	-0.008	4,303	3,730	4,327	3,744
Gender						
Male	–0.011	0.020	3,517	3,319	3,540	3,333
Female	–0.020	0.004	3,392	3,705	3,411	3,718
Time with Diabetes						
< 10 years	–0.036	0.002	3,982	1,705	4,003	1,719
≥ 10 years	0.004	0.024	2,980	4,832	3,001	4,846
Early enroller in study						
No	–0.011	0.004	2,269	2,048	2,290	2,061

Yes	–0.021	0.028	5,799	5,989	5,821	6,003

*Used in CEA analysis

**Used in Cost Offset analysis

VIII. RESULTS AND DISCUSSION

Results

Question 1: Does a nurse-managed diabetes foot clinic reduce foot wound rates in people with diabetes?

Yes, the nurse-managed diabetes foot clinic significantly reduced the number of foot wounds (12 fewer in the treatment group than the control group) occurring in high-risk and very-high-risk feet of adults who have had diabetes for more than 5 years. This was achieved with only a slight increase in the cost of patient care (see Question 3 analysis and discussion). Therefore, this clinic significantly reduced the risk for LEAs by reducing the number of foot wounds experienced by the treatment group.

Question 2: Does a nurse-managed diabetes foot clinic improve the health status of patients with diabetes?

No, the nurse-managed diabetes foot clinic did not significantly improve the health status of patients with diabetes, as evidenced by responses on the SF-36 Health Survey Version 2 answered at the first and final visits. In fact, although not statistically significant and the change was small, the health status of the treatment group declined slightly more than the control group. However, it should be noted that the treatment group was significantly older than the control group, which could explain this slight decline.

Question 3: Does a nurse-managed diabetes foot clinic reduce health care costs for patients with diabetes?

No, economic results from the nurse-managed diabetes foot study show that the intervention was more expensive than usual care, with an average added cost of $312 per participant.

Discussion

The intervention was significantly effective in reducing the number of foot wounds that occurred in diabetes patients, thus reducing the risk of foot wound infection and other sequelae (LEA). When divided by the number of reduced wounds that occurred (12), the intervention cost an additional $26 for each wound prevented. This is “cheap” to reduce the risk of LEAs.

Hospital data show that during the study period, 46 admissions for diabetic foot wounds occurred in non-study patients who received little to no foot care. At the lowest estimate of the average cost of treating a diabetic foot wound, $7,000 (Wu & Armstrong, 2006), this would have resulted in an estimated cost of $322,000 to BAMC to treat these wounds. At the high estimate, $45,000 (Wu & Armstrong), this would have resulted in an estimated cost to BAMC of $2,070,000. The actual cost likely lies between these two extremes, but is certainly greater than $312.

The cost-offset analysis, which sought to determine if this added cost resulted in savings from reduced health care usage was inconclusive. The treatment arm had lower health care costs, but this was not statistically different from the control group. When the cost of the intervention was added to the cost of health care utilization, the total costs were almost identical. This suggests that at very little additional cost, participants could have reduced foot-wound risk.

The cost-effectiveness analysis, which attempts to value the cost of the intervention in terms of cost per QALY, also provided somewhat inconclusive results. Data from the end of the trial suggest that the intervention was not cost effective compared to the control group; but this must be interpreted with caution because of several limitations.

Other Significant Findings:

One interesting finding was a positive correlation between CPT code costs and time-based costs. However, the correlation was moderate (0.22). This suggests that time was not always an accurate predictor of the amount of services provided to the participants. If the intervention were to be adopted by BAMC or other providers, efforts should be made to ensure that nurses are as efficient as possible and make referrals to providers or social service agencies when needed.

Limitations of the Study

A limitation of this study was the small sample size and the fact that it was a single-site trial. A larger sample was desired for this study as indicated in Table 1; however, the success of the pilot project for this study significantly reduced the pool of eligible individuals by 1,300 BAMC enrollees. All efforts were made to enroll and retain every qualified candidate. Statistical significance was achieved on the first research question, but answering the other two questions would have been assisted by a larger sample. Cost data varied widely, as is common with small samples and small effect sizes, and sufficient precision was not obtained with these data to make conclusive results.

Health care provided in military treatment facilities is not necessarily representative of health care treatment of the population at large; therefore, our findings cannot be generalized to other sites or to the general population. Enrollees in military treatment facilities receive high-quality health care at no cost to them. This eliminates financial deterrents to seeking regular and timely care for problems. Additionally, military patients receive prescription drugs free of charge, which should result in better adherence to treatment regimens for control of blood glucose and hypertension. In fact, the researchers were impressed that few study participants had

hemoglobin A1c levels above 8.0 (average blood sugar of 200 mg/dl). Blood pressure for most participants was controlled as well. Thus, timely and appropriate care should result in higher levels of health for the population served in military health care facilities.

Ideally an economic analysis projects the lifetime costs and benefits because the benefits from a clinical trial might accrue for patients long after the trial ends. Modeling lifetime costs and benefits was beyond the scope of this study, however, and only cost and effectiveness data for patients during the trial were compared. Therefore, our measure of QALYs might not be sensitive to effects that could become more prominent in the future.

IX. CONCLUSION AND IMPLICATIONS

Implications of the Study

This study demonstrated that a nurse-managed diabetic foot clinic that provides preventive foot care can reduce the number of foot wounds experienced by patients with diabetes who are at high risk and very-high risk for foot wounds at a low increase in cost to the government ($312 per participant). Because physicians normally have what they regard as higher priorities (managing blood glucose, serum cholesterol, blood pressure, and other clinical aspects of diabetes), foot assessment and care are often ignored.

A gap exists in the overall foot care of patients with diabetes, as demonstrated by the 46 admissions to BAMC during the study period of non-study participants who had received little foot care. This need for foot care can easily be fulfilled by registered nurses who are trained in foot care and diabetes education. The data suggest this is an economical way to reduce the risk of possible foot infections for people with diabetes. Although most RNs see this as outside their scope of practice, with proper training and proper patient referral for complications this is a role in which an RN can contribute to the overall foot health of patients with diabetes.

Suggestions for Future Research:

This study should be replicated at other sites within the military health care system using larger samples. The initially projected sample of 250, with 125 participants per group, would have doubled the study's power to answer research questions 2 and 3. This larger sample is necessary for the demonstrated small effect sizes.

X. SIGNIFICANCE OF RESEARCH TO MILITARY NURSING

"Medical surveillance of the U.S. military indicates that the incidence of all types of diabetes is similar to the civilian population (1.9 vs. 1.6 cases per 1,000 person-years) despite weight and fitness standards." (Paris, Bedno, Krauss, Keep, & Rubertone, 2001). Therefore, military personnel are at similar risks for the complications of diabetes as the general population.

Brooke Army Medical Center (BAMC) data for the 3 years of the study showed 46 hospital admissions for diabetic foot wounds that occurred in non-study patients. Only one had been provided foot care by a podiatrist. At the lowest estimated average cost of treating a diabetic foot wound, $7,000 (Wu & Armstrong, 2006), the estimated cost to BAMC of treating these wounds would be $322,000. At the high estimate, $45,000 (Wu & Armstrong), these admissions would have cost BAMC $2,070,000. The actual cost likely lies between these two extremes, but was certainly greater than $312 per patient.

Advance practice nurses in the military are an integral part of the care of patients with diabetes in the outpatient setting at military treatment facilities. Diabetes primarily affects those more than 40 years, targeting many soldiers nearing retirement and those newly retired. Once these soldiers retire, because of their unique skill sets, many continue to work for the government as Department of Defense civilians. Thus, their health is still important to the overall military effort.

Nurse practitioners empanel approximately 1,000 patients as primary care providers and care for patients with diabetes at almost every stage of development, including active duty soldiers. Additionally, nurse practitioners, clinical nurse specialists, and staff nurses provide care for soldiers, civil service employees, and contract employees with diabetes in deployed environments where the change in routines, stress, diet, activity, etc., wreak havoc on diabetes

control. The U.S. Army travels on its feet. This expanded scope of practice to include preventive foot care could contribute to the mission readiness of active-duty soldiers and government civilians who have diabetes by preventing foot wounds.

XI. REFERENCES

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XII. OUTCOMES RESULTING FROM THE STUDY

Publications

An article is in preparation to be submitted to *Diabetes Care* in 2008.

Abstracts or Other Materials

- Poster: 20th Annual Pacific Nursing Research Conference, Honolulu, HI, "Outcomes of a Nurse-Managed Diabetic Foot Clinic," March 22-24. 2007.
- Poster: 65th Annual Scientific Conference – American College of Foot and Ankle Surgeons, Orlando, Florida, March 14–18, 2007.
- Rose, B. S., Gilcreast, D. M., Mark, D. M., Lewis, P. C. "Outcomes of a Nurse-Managed Diabetic Foot Clinic," Delta Alpha At-Large Chapter Research & Scholarship Conference, Sister Mary Charles Frank Nursing Research Conference, January 10, 2007, International Conference Center, University of the Incarnate Word, San Antonio, Texas.
- Rose, B. S., Gilcreast, D. M., Mark, D. M., Lewis, P. C. "Outcomes of a Nurse-Managed Diabetic Foot Clinic," 18th Annual Sigma Theta Tau International Nursing Research Conference, Austria Conference Center, Vienna, Austria, July 11, 2007.

Presentations

- Podium Presentation: Rose, B. S., Gilcreast, D. M., Mark, D. M., Lewis, P. C. "Outcomes of a Nurse-Managed Diabetic Foot Clinic," Delta Alpha At-Large Chapter Research & Scholarship Conference, Sister Mary Charles Frank Nursing Research Conference, January 10, 2007, International Conference Center, University of the Incarnate Word, San Antonio, Texas.

- "Outcomes of a Nurse-Managed Diabetic Foot Clinic," Brooke Army Medical Center Diabetes Update Seminar, June 25, 2007.
- Podium Presentation: Rose, B. S., Gilcreast, D. M., Mark, D. M., Lewis, P. C. "Outcomes of a Nurse-Managed Diabetic Foot Clinic," 18th Annual Sigma Theta Tau International Nursing Research Conference, Austria Conference Center, Vienna, Austria, July 11, 2007.

Seminars, Lectures, and Workshops

- Brooke Army Medical Center Diabetes Update Seminar, June 25, 2007.

  Provided guest speakers on the topics of diabetic foot care, diabetes medications, nutrition plans for people with diabetes, and current treatment guidelines. Ms. Rose presented the results of the study at this all-day seminar. Outside nurses were also invited to attend.
- Dr. Gilcreast is scheduled to provide an hour continuing education activity for the Alamo Association of Diabetes Educators in January, 2008. The results of the study will be presented in this CE offering.

Patents or Licenses

None

Changes in Practice

Diabetic preventive foot care and education continues to be given by nurses at BAMC.

Changes in Policy

None

Press Coverage

None

APPENDIX A

Final Budget Report

BUDGET SUMMARIZATION TABLE

CATEGORY	ORIGINAL AWARD	EXPENSED TO DATE	PROJECTED EXPENSES TO END OF STUDY	REMAINING AMOUNT
Personnel	273,737.00	267,800.50		5,936.50
Consultant	30,500.00	10,990.00		19,510.00
Equipment	2,247.00	1,523.18		723.82
Supplies	6,411.00	5,147.29		1,263.71
Travel	1,800.00	1,528.14		271.86

Subcontract	102,690.00	83,070.66		19,619.34
Other Expenses	2,079.00	1,201.01		877.99
TOTAL	419,464.00	371,912.83		48,203.22
Indirect Costs	80,116.00	70,912.83		9,203.17
TOTAL	499,580.00	442,173.61		57,406.39

Discussion:

With the resignation of the advanced practice nurse in February 2006, Dr. Gilcreast's contract with the University of Texas Health Science Center at San Antonio was increased from 15% to 45% to allow her 18 hours per week to see participants and work on the study. Consultants and subcontracts cost were less than expected which may have been impacted by personnel turnover and less subject enrollment than anticipated.

APPENDIX B

Problems Encountered and Resolutions

Actual work on the study began in October 2004, when funding was released by the TSNRP, rather than the original August 2004. This placed the study 2 months behind the projected timeline.

A. Study Staff Turnover:

- Staff turnover was an issue because midway through the study (February 2006) both the project director (Mrs. Carolyn Garcia, RN) and the advanced practice nurse (LTC Deborah Bray, RN, CNS) left the study for other jobs. The project director believed she was underpaid given her experience and education, as identified in memos of 29 March 2005 and 23 May 2005. Increase in pay for PD was denied on 27 June 2005. LTC Bray was offered a full-time permanent government civil service position. A new project director, Ms. Janet Stansberry, RN, MSN, with considerable research experience was hired 2 February 2006 to replace the project director.
- Dr. Gilcreast had trained the data collection staff and participated in Wednesday and Thursday afternoon clinics. She monitored and evaluated the team members' skills and assessment for inter-rater reliability. With the resignation of the APN, Dr. Gilcreast and Principal Investigator Rose, took over seeing patients in clinic, thus increasing Dr. Gilcreast's effort on the study from 15% to 45%. Ms. Rose saw patients when Dr. Gilcreast was unable to. Because both Dr. Gilcreast and Ms. Rose were both highly skilled in assessing and treating diabetic feet, this did not change the inter-rater reliability of the data collectors.

- The inability to complete the study on the approved timeline was identified and stated in memos of 05 May 2005 and 29 March 2005. However, the study was completed on time with data collection ending on February 23, 2007, and analysis by the statistician and health care economist completed on June 30, 2007.
- Dr. Richard DeMouy, the health care cost expert originally on the study, unexpectedly left Choctaw and BAMC without informing the research team. A health care economist at Stanford University, Palo Alto, California, Dr. Todd Wagner, was identified to assist us in answering Question 3, the cost analyses. Dr. Wagner provided outstanding information and was a definite asset to the team. He devised a data collection form to assist in collecting the necessary information. Data were obtained from BAMC's Hospital Resource Management Office, allowing comparison of our results to data for BAMC enrollees who did not take part in the study. From HRMO information, 46 patients with diabetes were admitted to the hospital for diabetic foot wounds during the time period of the study. None of these were participants in the foot care study and only one had received any documented foot-related referrals to a podiatrist.

B. Recruitment and retention:

- Recruitment began in March, 2005. The team identified the inability to meet recruitment goals of 25 participants/month as stated in memos of 29 March 2005 and 27 July 2005 to TSNRP.

- The PI, Ms. Rose, and team members met with clinic staff and presented information about the study for referrals providing the objectives of the study. Lists of patients with diabetes were obtained from the clinic files and provider referrals to enable calling of prospective participants.
- One problem was that the 1,300 BAMC patients enrolled in the pilot diabetes foot clinic continued to be seen in those clinics and were not available for recruitment into the present study because it was desired that the participants in this study have no prior experience with a nurse-run foot clinic. These patients were also very happy with the foot care they were receiving. This reduced the pool of study-eligible patients with diabetes enrolled at BAMC.
- A proposal to increase percentages of effort for both the project director and the advanced-practice nurse from 80% to 100% effort to enable recruitment from Wilford Hall Medical Center and a request to include mileage for the additional 26-mile of travel, as outlined in a memo dated 20 April 2005, was denied.
- As of December, 2005, 128 participants were enrolled (64 treatment group, 64 control group). See previous information under “IV. Results” about the immediate loss of two participants, which resulted in 62 in the treatment group and 64 in the control group. December 2005 was established as the “cut-off” date for enrollment because of the need to follow participants for 12 months and the ending of the funding period. By this time, we had exhausted the pool of candidates for the study enrolled at BAMC.
- Data were entered and verified as they were collected. Data collection was completed on February 23, 2007.

- The overall number of dropouts from the study was 17 subjects (13%) leaving 111 participants who completed the study, 54 control and 57 treatment participants. According to a recent study on recruitment and retention, 18% was the dropout rate from a diabetes self-management study (Thoolen, deRidder, Bensing, Gorter, & Rutten, 2007). Therefore, our drop-out rate was similar to that experienced by others. Reasons for dropping out from the present study were mainly: (1) Did not want to be in control group. “Why come if you aren’t going to cut my toenails and file my calluses?” (2) “It is too far to come.” Many of BAMC’s enrollees live as far as 50 miles from the facility. (3) Conflicts with work schedules (40% of participants were less than 60 years of age).

APPENDIX C

Psychometric Report

Reliability and Validity of Measures

Principal Investigator – Contact Information

Name: Beverly S. Rose
Address: [redacted]
Telephone Number: Work: [redacted]
Home:
E-mail: [redacted]

Title of **Study**: Outcomes of a Nurse-Managed Diabetic Foot Clinic

Demographic Characteristics of Sample

Total sample size 126 Age Range: 23-87 yrs.

	<19 yrs	19-60 yrs	>60 yrs	Other
Male	**0**	**10**	**66**	**0**
Female	**0**	**6**	44	**0**

Number	Service
Info not obtained	Army
Info not obtained	Air Force
Info not obtained	Navy
Info not obtained	Marine

Number	Race:	
63	Caucasian	
29	African-American	
22	Hispanic	
4	Asian/Pacific Islander	
8	Other (Describe)	1 Declined to answer, 1 Middle Eastern, 1 Native American 2 Filippino

Number	Service Component:
3	Active Duty
Info not obtained	Retired
Info not obtained	Reserve
Info not obtained	National Guard
Info not obtained	Dependent

Briefly describe defining characteristics of sample:

Adults with diabetes mellitus Types 1 or 2 for at least 5 years, ages 23-87 yrs. (mean 64), eligible for health care at the Brooke Army Medical Center. There were 62 participants in the treatment group and 64 participants in the control group. The treatment group (mean 65 yrs.) was significantly older than the control group (mean 62 yrs., p=0.003). The sample was 60% male and 40% female. Ethnicity was 50% Caucasian, 23% African-American, 18% Hispanic, 3% Asian-American, and 9% Other. High-risk feet comprised 59% of the sample and very-high-risk feet were 41% of the sample. Our estimate was 66% high-risk feet and 34% very-high risk feet. Mean duration of diabetes was Treatment Group 13 yrs., control group 12 yrs.

Instrument Reference					
Title:	SF-36 Health Survey Version 2.0			N of Scales:	8
Year:	1992			Edition:	V. 2.0
Authors:	Ware, J.E., Kosinski, M. & Dewey, J. E.				
Publisher:	The Medical Outcomes Trust and Quality Metric Inc.		Journal/Book Title:	How to Score Version 2.0 of theSF-36 Health Survey – Standard & Acute Forms	
Year:	2002	Volume:	1	Page Numbers:	5

Tool Modifications

Did you modify this tool?	☐ Yes (Answer A & B below) x No
A. Briefly describe why modifications were made:	**N/A**
B. Describe what modifications were made (attach page if additional space is needed):	N/A

Directions: Please indicate any reliability and/or validity testing you have done on this tool by placing a check mark next to the procedure. To the right of the procedure, please report your findings. If individual scales were tested for reliability, please report findings of each scale.

Check all that apply

Reliability	Validity
☐ Internal-Consistency Reliability	Content Validity
X Cronbach Coefficient Alpha for 8 scales .78-.93 (M = 0.85)	☐ Index of Content Validity (CVI)
☐ Kuder- Richardson (KR-20)	☐Other (please describe on back of form)
☐ Interrator Reliability	Criterion-Validity
☐ Intrarater Reliability	☐ Predictive
☐ Coefficient of Stability (test-retest)	☐ Linear Correlation
☐ Coefficient of Equivalence	Name of Criterion Measure Used:
☐ Other (please describe on back of form)	☐ Concurrent
	☐Linear Correlation
Reliability of Individual Scales	Name of Criterion Measure Used:
Scale Name / Reliability	Construct Validity (include a copy of findings)
Physical Health .94	☐ Multitrait-Multimethod
Physical Role .95	☐ Hypothesis testing
Bodily Pain .85	☐ Contrasted Group
General Health .83	☐ Factor Analysis
Vitality .85	☐ Exploratory
Social Functioning .88	
Role Emotional .93	☐ Confirmatory
Mental Health .85	☐ Other (please describe on back of from)

Evaluation of Measure

Would you recommend the use of this measure in your population to other researchers? Use extra page, if needed.

× Yes. Please explain why. Provided an easy universal measurement of overall health of participants.

☐ No Please explain why.

APPENDIX D

Research Categorization Using TSNRP Areas of Research

Identify the main research priority investigated in this research study.
Please check one item for Primary (Required) and one item for Secondary Priority Areas (if appropriate)

Primary Research Priority Area: (Required)

___ Military Deployment Health

_X_ Translating Knowledge & Research Findings into Practice in a Military Context

___ Evidence Based Practice

___ Recruitment & Retention of the Military Nursing Workforce

___ Developing & Sustaining Military Nursing Competencies

Secondary Research Priority Area:

___ Military Deployment Health

___ Translating Knowledge & Research Findings into Practice in a Military

X_ Evidence Based Practice

___ Recruitment & Retention of the Military Nursing Workforce

___ Developing & Sustaining Military Nursing Competencies

Other *(fill in)* _____

Identify 3-5 key words relating to the proposal. (Required)
(You MUST use the *CRISP Thesaurus* for key words. The thesaurus is on the web at:
http://crisp.cit.nih.gov/crisp/crisp_help.help

1. Prevention of amputation in patients with diabetes
2. Nurse-Managed Clinic
3. Diabetic Foot Preventive Care
4. Reduction of foot wounds

APPENDIX E

Do you have any articles or presentations 'in press' ☐ **yes** ☒ **no**

If yes, provide copies and all PAO clearance information. All citations listed must be in APA format.

APPENDIX F

Copies of Surveys and Data Collection Forms